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Date: March 29, 2011 Name: Jason W. Schigelone, Reg. No. 56,243 Signature: /Jason W. Schigelone/

Attorney Docket No.: 12730-11
Client Ref. No.: PA-5327-CIP

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Osbourne *et al.*	
Serial No.: 10/642,513	Examiner: William H. Matthews
Filing Date: August 15, 2003	Group Art Unit No.: 3774
For: Stent and Method of Forming a Stent with Integral Barbs	Confirmation No.: 3839

APPEAL BRIEF

Mail Stop Appeal Brief
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

By filing this Appeal Brief in accordance with 37 C.F.R. § 41.37, Appellant respectfully requests review of the grounds of rejection in the present application.

TABLE OF CONTENTS

I. REAL PARTY IN INTEREST

The real party in interest is Cook Incorporated, the assignee of record in the present application.

II. RELATED APPEALS AND INTERFERENCES

This is the second appeal to the Board in the present application. The first appeal was filed on November 14, 2007 and was decided by the Board on October 14, 2009. The present appeal involves the same claims, and the same reference (U.S. Patent No. 5,800,526), considered by the Board in the first appeal.

Appellant is not aware of any other prior or pending appeals, judicial proceedings or interferences that may be related to, directly affect, or be directly affected by or have a bearing on the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

Claims 1-44 are canceled.

Claims 47, 51, 52, 54-57, 59, 63, and 64 are withdrawn from consideration.

Claims 45, 46, 48-50, 53, 58, and 60-62 are rejected as obvious in view of U.S. Patent No. 5,800,526, in combination with U.S. Patent Application Publication No. 2001/0027339.

The rejection of these claims is being appealed.

IV. STATUS OF AMENDMENTS

Appellant has not filed any amendment subsequent to the final rejection dated June 22, 2010.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Independent claim 45 is directed to a barbed stent for deployment within the body of a patient, as shown for example in Figures 87-92. The barbed stent 355 includes a wire 352 having at least one integrally formed barb 357 configured to engage tissue adjacent to the stent. The wire 352 includes at least one bend connecting to at least two struts such that the barb 357 points in a predetermined direction at an angle relative to the longitudinal axis 359 of the stent 355, as shown for example in Figures 90b and 91. (*See* Application; p. 62, line 28 – p. 63, line 7 (¶215)). The barb 357 is unbent with respect to the wire 352 and is free from weakening due to bending. (*See id.*; p. 4, lines 17-28 (¶18), p. 61, lines 10-14 (¶205)).

Dependent claim 46 recites that the wire 322 may have a zig zag shape, as shown for example in Figures 86a and 86b. (*See id.*; p. 61, lines 24-29 (¶208)). Such a zig zag shape of the barbed stent is also shown in Figures 90a and 90b (*see id.*; p. 62, line 28 – p. 63, line 7 (¶215) and in Figure 91 (*see id.*; p. 63, lines 11-16 (¶217)).

Dependent claim 48 recites that the barb 357 may point in a direction at a generally transverse angle relative to the longitudinal axis 359 of the stent 355, as shown for example in Figures 90b and 91. (*See id.*; p. 62, line 28 – p. 63, line 7 (¶215)).

Dependent claim 49 recites that the barb 314 is positioned on the bend 326 of the wire 322, as shown for example in Figures 86b and 91. (*See id.*; p. 61, lines 24-29 (¶208)).

Dependent claim 50 recites that each bend includes at least one barb 357 positioned thereon, as shown for example in Figures 90a, 90b and 91. (*See id.*; p. 62, line 28 – p. 63, line 7 (¶215)).

Dependent claim 53 recites that the stent is adjacent to a proximal end of an endoluminal prosthesis, as shown for example in Figure 91. (*See id.*; p. 25, lines 27-28 (¶119)).

Independent claim 58 is directed to an endoluminal prosthesis including a substantially cannular body with proximal and distal ends. Referring to Figure 91, the stent 360 is affixed to the substantially cannular body 362 near the proximal end (*see id*; p. 25, lines 27-28 (¶119)), and the stent 360 includes a wire having at least one integrally formed barb 364 that has not been attached to the stent 360 during the manufacturing process and is configured to engage tissue adjacent the stent 360. The wire includes at least one bend connecting to at least two struts such that the at least one barb 364 points in a predetermined direction at an angle relative to a longitudinal axis 366 of the stent 360. (*See id.*; p. 62, line 28 – p. 63, line 16 (¶215-¶217)). The barb 364 is unbent with respect to the wire and is free of weakening due to bending. (*See id.*; p. 61, lines 10-14 (¶205)).

Dependent claim 60 recites that the stent 360 is in a zigzag shape, as shown for example in Figure 91. (*See id.*; p. 63, lines 11-16 (¶217)).

Dependent claim 61 recites that the barb 314 is positioned on the at least one bend 326 and/or at least one of the at least two struts 328, as shown in Figures 86a, 86b, and 91. (*See id.*; p. 61, lines 24-29 (¶208)).

Dependent claim 62 recites that the barb 357, 374 points in a direction at one of an acute angle and a generally transverse angle relative to the longitudinal axis 359, 376 of the stent 355, 372, as shown for example in Figures 90b, 91, and 92. (*See id.*; p. 62, line 28 – p. 63, line 7 (¶215); and p. 63, lines 17-24 (¶218)).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Appellant respectfully requests that the Board review the Examiner's rejection of claims 45, 46, 48-50, 53, 58, and 60-62 as unpatentable under 35 U.S.C. § 103(a) in view of U.S. Patent No. 5,800,526 and U.S. Patent Application Publication No. 2001/0027339.

VII. ARGUMENT

A. The Board Has Already Considered, And Rejected, The Examiner's Findings Regarding U.S. Patent No. 5,800,526.

1. The First Appeal

The present claims are directed to a barbed stent for deployment within the body of a patient. The claims recite, among other things, a wire having:

1) at least one ***integrally formed barb***, that
2) ***points in a predetermined direction*** at an angle relative to a longitudinal axis of the stent, where
3) the ***integral barb is unbent with respect to the wire and is free of weakening due to bending***.

On November 14, 2007, Appellant appealed the Examiner's rejection of the present claims as anticipated by U.S. Patent No. 5,800,526 ("Anderson"). The Examiner argued on appeal, among other things, that Anderson disclosed barbs that are unbent with respect to a stent wire. (*See* Section X; BPAI Opinion; p. 4). On October 14, 2009, the Board issued an opinion reversing the Examiner's rejection, and rejecting the Examiner's assertion that Anderson discloses a stent according to the present claims. The Board found, among other things, that "the barbs 20 of Anderson are not necessarily unbent with respect to the stent wire." (See *id.* at 5). Accordingly, the Board held that "the Examiner erred in determining that the integral barbs of Anderson are unbent with respect to the stent wire. (See *id.* at 6) (emphasis added).

2. The Present Appeal

Appellant's claims have not been amended since this Board's prior decision in October 2009. Notably, the present claims still recite, among other things, integral barbs that are unbent with respect to a stent wire – a feature that this Board explicitly held Anderson does not disclose.

Following the Board's decision, the Examiner rejected Appellant's claims as invalid in view of Anderson, in combination with U.S. Patent Application Publication No. 2001/0027339 ("Boatman"). The Examiner's primary argument is essentially the same argument that this Board already considered and rejected – that Anderson discloses, or appears to disclose, a stent with unbent barbs. (*See, e.g.,* Final Office Action dated June 22, 2010; pp. 2-5). According to the Examiner:

> ***The Board determined*** that Anderson did not necessarily disclose the bending location was not at the barb because ***Anderson's disclosure contains a contradiction***. The specification describes the barbs being bent outward while ***Figure 7 shows the 'bent' state, and the barbs 20 are not bent with respect to the arches 18.***"

This argument distorts the Board's decision, which clearly expressed disagreement with the Examiner's position that Figure 7 of Anderson disclosed unbent barbs:

> ***[T]he Examiner points to Figures 4-7 of Anderson to show that*** because both wire bends 18 and barbs 20 face outwardly, ***the barbs 20 are not bent with respect to the wire***. . . . In other words, the Examiner appears to take the position that because material has been removed in areas of the barbs 20, during expansion of the stent 10 the wire 18 will bend at these regions such that barbs 20 will be oriented outwardly but will not bend with respect to the wire. ***We disagree with the Examiner's position*** . . . .

(*See* Section X; BPAI Decision; p. 4) (emphasis added).

On the contrary, the Board expressly found that the Examiner's position was antithetical to Anderson's teachings:

> In this case, Anderson also teaches uniform radial expansion of the stent 10 without substantial out-of-plane twisting. Anderson, col. 8, ll. 17-19. Accordingly, ***if the wire 18 undergoes bending to orient the barbs 20 outwardly, as the Examiner suggests, then the stent 10 will also likely undergo out-of-plane twisting, which is in contrast to Anderson's specific teachings***.

(*Id.* at 5) (emphasis added).

The Board has already determined that the Examiner erred in finding that Anderson discloses integral barbs that are unbent with respect to a stent wire. The

Examiner's continuing assertion that Anderson discloses, or appears to disclose, unbent barbs is clear and inexcusable error.

B. The Examiner Has Failed To Establish A *Prima Facie* Case Of Obviousness.

The Examiner asserts that the present claims would have been obvious in view of the combination of Anderson and Boatman. The Examiner fails to establish that either of these references, alone or in combination, discloses, teaches, or suggests the claimed invention.

The Examiner bears the initial burden of establishing a *prima facie* case of unpatentability. *See e.g., In re Rijckaert*, 9 F.3d 1531, 1532 (Fed. Cir. 1993); *In re Oetiker,* 977 F.2d 1443, 1445 (Fed. Cir. 1992). If that burden is not met, then, without more, the applicant is entitled to a patent. *Id.* To establish a *prima facie* case of obviousness based on a combination of references, the examiner must articulate the particular basis for the conclusion that the combination would have been obvious. *In re Kahn*, 441 F.3d 977, 986 (Fed. Cir. 2006). An obviousness analysis must be explicit and cannot be sustained by mere conclusory statements. *KSR v. Teleflex*, 550 U.S. 398, 418 (2007). Rather, "there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006); *KSR v. Teleflex*, 550 U.S. 398, 418 (2007).

To prevent the use of hindsight, the examiner must identify some reason or motivation one of ordinary skill in the art would have had to choose particular references for combination. *KSR v. Teleflex*, 550 U.S. 398, 418 (2007); In *re Rouffet*, 149 F.3d 1350, 1357 (Fed. Cir. 1998) (reversing Board's finding of obviousness as clearly erroneous due to failure to provide any proper motivation to combine references). Hindsight is inferred when the fact-finder fails to explain the specific understanding or principle that would have motivated a skilled artisan to combine particular references. *In re Kahn*, 441 F.3d 977, 986 (Fed. Cir. 2006); *In re Rouffet*, 149 F.3d 1350, 1358 (Fed. Cir. 1998).

1. Anderson Does Not Disclose The Claimed Invention.

a. Anderson Does Not Disclose, Teach, Or Suggest An Integral Barb That Is Unbent With Respect To The Wire And Is Free Of Weakening Due To Bending.

As explained above, the Board has already held that Anderson does not disclose a stent with integral barbs that are unbent with respect to a stent wire. Nonetheless, the Examiner contends that Figure 7 of Anderson, by itself, discloses, or appears to disclose, unbent barbs. The Examiner does not identify where in Figure 7 Anderson discloses that the anchors 20 are unbent, nor does he provide any evidence or argument that one of ordinary skill in the art would have understood that Figure 7 shows anchors 20 that are unbent. In addition, the Examiner fails to explain why one of ordinary skill in the art would have viewed Figure 7 in isolation and ignored the Anderson specification, which explains that the stent is designed "so that ***the barbs will bend outwardly*** when the stent is expanded." (*See* Anderson; col. 9, lines 16-26) (emphasis added).

Instead, ***the Examiner shifts the burden to Appellant to prove that Figure 7 does not disclose this feature***. (*See* Final Office Action dated June 22, 2011; p. 3 ("Applicant has not explained how Figure 7 shows 'a bent barb'. Furthermore, Applicant has not shown that Figure 7 would not reasonably suggest a barb that is unbent with respect to Arch 18 . . . ."). This is improper. *See, e.g., In re Rijckaert*, 9 F.3d at 1534 ("While the [PTO] criticizes [applicant's] arguments regarding the § 103 rejections, ***the burden to rebut a rejection of obviousness does not arise until a prima facie case has been established***. In the case before us, it was not.") (emphasis added)).

The Examiner's reliance on Figure 7 is misplaced, in any event, as this figure is not drawn to scale and does not describe the nature of the connection between the anchors 20 and valleys 18 of cylindrical rings 12. *See, e.g., Nystrom v. Trex Co., Inc.*, 424 F.3d 1136, 1149 (Fed. Cir. 2005) (noting that "the principles set forth in our prior precedents [include] that arguments based on drawings not explicitly made to scale in issued patents are unavailing"); citing *Hockerson-Halberstadt, Inc. v. Avia Group Int'l,*

Inc., 222 F.3d 951 (Fed. Cir. 2000). To be sure, Figure 7 does not even include reference numbers for the anchors and valleys, nor does it show with any particularity the connection between the anchors 20 and the valleys 18 of cylindrical rings 12:

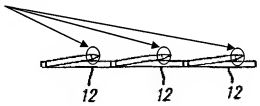
FIG. 7

Anderson; Figure 7

It is impossible to tell from Figure 7, alone, that the anchors 20 are "unbent with respect to the wire," or that the anchors 20 are "free of weakening due to bending," as recited in all of the pending claims.

- Unbent?
- Free of Weakening?

FIG. 7



Anderson; Figure 7
(modified to indicate anchors 20)

On the other hand, Anderson's specification clearly contemplates that the barbs in Figure 7 will be bent. (*See* Anderson; col. 9, lines 16-26).

The Examiner's finding that Anderson discloses, or appears to disclose, a stent with integral barbs that are unbent with respect to a stent wire and free of weakening

due to bending ignores the Anderson specification, and ignores the record in this case. Accordingly, this finding should be rejected.

b. *Anderson Does Not Disclose, Teach, Or Suggest, An Integral Barb That Points In A Predetermined Direction At An Angle Relative To A Longitudinal Axis Of The Stent.*

The present claims recite an integral barb that "points in a predetermined direction at an angle relative to a longitudinal axis of the stent." In contrast, Anderson disparages stents where "exact placement of an anchoring stent . . . [is] critical for properly securing the stent," and instead provides a stent with "a plurality of barbs throughout the entire circumference of the stent . . . ***so that exact placement of the anchors is less critical***." *See* Anderson; col. 3, lines 5-8; col. 3, lines 33-39) (emphasis added). In other words, Anderson describes barbs pointing in an ***arbitrary, undetermined direction***.

The Examiner argues that "Anderson desires the barbs to point outwardly in response to a bending action, and outwardly is a direction." (*See* Final Office Action dated June 22, 2010 at 2). This argument misses the point. Indeed, the present claims are not directed to stents with barbs that merely point in ***any*** outward direction – they are directed to stents with barbs that point in a ***predetermined*** outward direction.

In particular, the claims recite that the at least one integrally formed barb is "configured to engage tissue adjacent the stent," which makes it clear that the barb does not point away from tissue adjacent the stent (*e.g.*, "inwardly"). In addition, the claims recite that the at least one barb points "at an angle relative to a longitudinal axis of the stent," which makes it clear that the barb must point in a direction ***away from*** the longitudinal axis of the stent that is not inwardly – ***i.e., "outwardly."*** Finally, the claims recite that the at least one barb points "in a ***predetermined direction***," which makes it clear that the barb cannot point in ***any*** outward direction – it must point in a ***predetermined outward direction***.

The Examiner's suggestion that any outward direction is a predetermined direction improperly renders this feature meaningless, and should be rejected. *See, e.g., Stumbo v. Eastman Outdoors, Inc.*, 508 F.3d 1358, 1362 (Fed. Cir. 2007) ("[C]onstruing the word 'vertical' as referring to merely the orientation of the opening would render the phrases 'along one of said side edges' and 'along one vertical corner of said structure' superfluous, a methodology of claim construction that this court has denounced"); *see also, e.g., Cat Tech. LLC v. Tubemaster, Inc.*, 528 F.3d 871, 885 (Fed. Cir. 2008) (rejecting construction that rendered claim language meaningless); *Bicon, Inc. v. The Straumann Co.*, 441 F.3d 945, 950-51 (Fed. Cir. 2006) (same).

2. The Examiner Has Failed To Show That Boatman Makes Up For Anderson's Deficiencies.

The Examiner does not contend that Boatman discloses a stent with an integral barb that is unbent with respect to the stent wire and is free of weakening due to bending, nor does he contend that Boatman discloses such a barb that points in a predetermined outward direction at an angle relative to a longitudinal axis of the stent. Moreover, the Examiner does not contend that Boatman would have motivated one of ordinary skill in the art to modify the Anderson stent to include both of these features. Accordingly, the Examiner has failed to establish a *prima facie* case of obviousness.

3. The Examiner Has Failed To Provide Proper Motivation To Combine Boatman.

Notwithstanding the Examiner's position that Figure 7 of Anderson discloses, or appears to disclose, an unbent barb, the Examiner argues that one of ordinary skill would have combined Boatman "to ensure the barbs in Anderson are free of unnecessary bending stresses." (See Final Office Action, dated June 22, 2010 at 5). The Examiner fails to explain why one of ordinary skill in the art would have been motivated to look for a reference outside of Anderson, particularly if this person believed, (as the Examiner apparently does), that Anderson already discloses a stent with unbent barbs as claimed. It defies logic to suggest that one of ordinary skill

would have selected Anderson because it discloses a stent with unbent barbs, and then would have sought out another reference to ensure that the barbs were actually unbent. Because the Examiner failed to provide any proper motivation to select or combine Boatman, it must be assumed that the Examiner has engaged in improper hindsight. *See In re Rouffet*, 149 F.3d at 1358 (reversing Board's finding of obviousness as clearly erroneous due to failure to provide any proper motivation to combine references).

Even assuming, for the sake of argument, that one of ordinary skill was aware of Boatman, the Examiner has failed to show that Boatman would have motivated the skilled artisan to modify Anderson to arrive at the claimed invention. The Examiner cites paragraphs 24, 81, and 84 of Boatman for the proposition that stents may be designed to provide bending "over only certain curvilinear struts, while other sections of the stent do not deform." (*See* Final Office Action at p. 5). He then states, ***without any citation or support***, that "it would have been apparent to one of ordinary skill in the art to provide the greatest fatigue life at the thinner barb junctions of a stent in order to prevent fracture and release of the barbs into the bloodstream." (*See id.*) The Examiner then concludes, ***again without any support***, that it would have been obvious to one of ordinary skill in the art to "remove[] material ***only along the thicker curvilinear struts 12*** [of Anderson] such that the arches 18 bend outwardly to direct the barbs 20 to face outwardly (as shown in figure 7 of Anderson)." *See id.* (emphasis added).

The Examiner fails to cite any evidence that one of ordinary skill would have been concerned about the fatigue life of the barbs of the Anderson stent, or would have been motivated to modify the Anderson stent to improve fatigue life of the barbs. To the contrary, the Examiner's contention that Anderson discloses, or appears to disclose, a stent with unbent barbs suggests that the skilled artisan would not have needed to be concerned with the fatigue life of Anderson's barbs.

Even if one of ordinary skill was concerned about the fatigue life of Anderson's barbs, which Appellant does not concede, none of the paragraphs of Boatman cited

by the Examiner describes barbs, or problems associated with barb attachment or fatigue, nor do these paragraphs describe selectively removing material from portions of a stent to provide an unbent barb that is free of weakening due to bending. Indeed, none of these paragraphs describes modifying a stent to eliminate fatigue or weakening between a barb and a wire. The Examiner fails to explain how Boatman is relevant, or why a person of ordinary skill would have even considered Boatman for reducing barb fatigue life.

The paragraphs of Boatman cited by the Examiner refute, rather than support, the Examiner's conclusion regarding obviousness. According to the Examiner, the skilled artisan would have been motivated by Boatman to provide selective points of stress along Anderson's struts, with the hope of preventing the Anderson anchors from bending and weakening due to bending. But paragraph 84 of Boatman teaches just the opposite – that, whereas prior art stents "plastically deform at points of stress," the Boatman stents "distribut[e] lateral bending forces over the curvilinear struts." *See* Boatman; ¶84. Thus, paragraph 84 of Boatman appears to ***teach away*** from the Examiner's proposed modification of the Anderson stent.

Likewise, the Examiner's proposed modification runs counter to the Anderson specification. In particular, the Examiner's conclusion that one of ordinary skill would have removed material "***only along the thicker curvilinear struts 12***" suggests that the skilled artisan would ***not*** have removed material in the area of the barbs 20. But this directly contradicts Anderson's express teaching of step etching "in the areas of the attachment elements or barbs 20 . . . . ***so that the barbs will bend outwardly when the stent is expanded.***" (*See* Anderson; col. 9, lines 16-22, Section X; BPAI Decision; p. 4) (emphasis added).

4. The Examiner Has Failed To Show That The Proposed Combination Would Yield A Stent Of The Presently Claimed Invention.

Finally, the Examiner has failed to provide any evidence that the combination of Anderson and Boatman would yield a stent falling within the scope of the present

claims. As explained above, Anderson expressly teaches a stent design with barbs that bend outwardly when the stent is expanded. Neither Anderson, nor Boatman, discloses a stent design with integral barbs that do not bend outwardly when the stent is expanded, or a stent design with integral barbs that are free of weakening due to bending. Moreover, neither Anderson nor Boatman discloses a stent design with integral barbs that point in a predetermined direction at an angle relative to a longitudinal axis of the stent. Thus, neither reference explicitly or implicitly discloses, teaches, or suggests a stent with all of the features of the present claims.

The Examiner's finding that the proposed combination would result in a stent falling within the scope of the present claims is pure speculation that cannot support a finding of obviousness. *See, e.g., In re GPAC Inc.*, 57 F.3d 1573, 1582 (Fed. Cir. 1995) (holding that the Board's conclusory statements regarding the prior art "lack[] the factual basis required to validate a claim rejection under section 103."); *citing In re Warner*, 379 F.2d 1011, 1017 (CCPA 1967) ("The Patent Office has the initial duty of supplying the factual basis for its rejection. It may not, because it may doubt that the invention is patentable, resort to speculation, unfounded assumptions or hindsight reconstruction to supply deficiencies in its factual basis.").

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C. CONCLUSION

Neither Anderson nor Boatman, alone or in combination, discloses, teaches, or suggests a stent with each and every feature recited in the present claims. Moreover, the Examiner has failed to establish that one of ordinary skill would have been motivated to combine Boatman, or that the combination would result in the claimed invention. Accordingly, the Examiner has failed to establish a *prima facie* case of obviousness and the present rejection is improper. Appellant respectfully requests that the Board reverse the present rejection.

Respectfully submitted,

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VIII. CLAIMS APPENDIX

1-44. (Canceled)

45. (Previously presented) A barbed stent for deployment within the body of a patient, comprising:

a wire having at least one integrally formed barb that has not been attached to the wire during the manufacturing process, configured to engage tissue adjacent the stent;

wherein the wire comprises at least one bend connecting to at least two struts such that the at least one barb points in a predetermined direction at an angle relative to a longitudinal axis of the stent, wherein the at least one barb is unbent with respect to the wire and is free of weakening due to bending.

46. (Previously presented) The stent of claim 45, wherein the wire is in a zigzag shape.

47. (Withdrawn) The stent of claim 45, wherein the at least one barb points in a direction at an acute angle relative to the longitudinal axis of the stent.

48. (Previously presented) The stent of claim 45, wherein the at least one barb points in a direction at a generally transverse angle relative to the longitudinal axis of the stent.

49. (Previously presented) The stent of claim 45, wherein the at least one barb is positioned on the at least one bend.

50. (Previously presented) The stent of claim 45, wherein each of the at least one bend comprises at least one barb positioned thereon.

51. (Withdrawn) The stent of claim 45, wherein the at least one barb is positioned on at least one of the at least two struts.

52. (Withdrawn) The stent of claim 45, wherein each of the at least two struts comprises at least one barb positioned thereon.

53. (Previously presented) The stent of claim 45, wherein the stent is adjacent a proximal end of an endoluminal prosthesis.

54. (Withdrawn) The stent of claim 53, wherein the at least two struts extend away from the proximal end of the endoluminal prosthesis in a proximal direction.

55. (Withdrawn) The stent of claim 54, wherein the endoluminal prosthesis is adapted to be deployed at least partially within the aorta, so that the stent extends at least partially above a renal artery when the prosthesis is implanted.

56. (Withdrawn) The stent of claim 53, wherein the prosthesis is a bifurcated aortic prosthesis.

57. (Withdrawn) The stent of claim 45:

wherein the wire is in a zigzag shape and the at least one barb points in a direction at one of an acute angle and a generally transverse angle relative to the longitudinal axis of the stent, the at least one barb being positioned on one of:

a) the at least one bend; and

b) at least one of the at least two struts; and

wherein the stent is adjacent a proximal end of a bifurcated aortic endoluminal prosthesis, the at least two struts of the stent extending away from the

proximal end of the endoluminal prosthesis in a proximal direction, the endoluminal prosthesis being adapted to be deployed at least partially within the aorta, so that the stent extends at least partially above a renal artery when the prosthesis is implanted.

58. (Previously presented) An endoluminal prosthesis comprising:

a substantially cannular body having proximal and distal ends; and

a stent affixed to the substantially cannular body near the proximal end, the stent comprising a wire having at least one integrally formed barb that has not been attached to the wire during the manufacturing process, configured to engage tissue adjacent the stent;

wherein the wire comprises at least one bend connecting to at least two struts such that the at least one barb points in a predetermined direction at an angle relative to a longitudinal axis of the stent, wherein the at least one barb is unbent with respect to the wire and is free of weakening due to bending.

59. (Withdrawn) The prosthesis of claim 58, wherein the substantially cannular body is bifurcated.

60. (Previously presented) The prosthesis of claim 58, wherein the stent is in a zigzag shape.

61. (Previously presented) The prosthesis of claim 58, wherein the at least one barb is positioned on one of:

a) the at least one bend; and

b) at least one of the at least two struts.

62. (Previously presented) The prosthesis of claim 58, wherein the at least one barb points in a direction at one of an acute angle and a generally transverse angle relative to the longitudinal axis of the stent.

63. (Withdrawn) The prosthesis of claim 58, wherein at least a portion of the stent extends proximally away from the proximal end of the cannular body.

64. (Withdrawn) The prosthesis of claim 58:

wherein the stent is in a zigzag shape and the at least one barb points in a direction at one of an acute angle and a generally transverse angle relative to the longitudinal axis of the stent, the at least one barb being positioned on one of:

a) the at least one bend; and

b) at least one of the at least two struts; and

wherein the substantially cannular body is bifurcated and at least a portion of the stent extends proximally away from the proximal end of the cannular body.

IX. EVIDENCE APPENDIX

None.

X. RELATED PROCEEDINGS APPENDIX

Attached is a copy of the decision of the Board of Patent Appeals and Interferences, dated October 14, 2009, in the present application.

UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/642,513	08/15/2003	Thomas A. Osborne	12730-11	3839

757 7590 10/15/2009

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ART UNIT	PAPER NUMBER
3774	
MAIL DATE	DELIVERY MODE
10/15/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte THOMAS A. OSBORNE and JASON A. MEAD

Appeal 2009-002753
Application 10/642,513
Technology Center 3700

Decided: October 14, 2009

Before WILLIAM F. PATE, III, MICHAEL W. O'NEILL, and STEFAN STAICOVICI, *Administrative Patent Judges*.

STAICOVICI, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Thomas A. Osborne et al. (Appellants) appeal under 35 U.S.C. § 134 from the Examiner's decision rejecting claims 45, 46, 48-50, 53, 58, and 60-62. Claims 47, 51, 52, 54-57, 59, 63, and 64 have been withdrawn and claims 1-44 have been cancelled. We have jurisdiction over this appeal under 35 U.S.C. § 6 (2002).

THE INVENTION

The Appellants' invention relates to a stent with barbs 314 integral with the stent wire 322, where the barbs are not attached to the stent wire during manufacturing. Spec. 1, ¶ [0005]. That is, the barbs 314 are cut into the stent wire 322 and the wire is bent into a suitable stent wire shape such as to orient the barbs in a desired direction in relation to the longitudinal axis of the final stent shape. Spec. 59, ¶ [0198]; Spec. 61, ¶¶ [0204] and [0205]; and figs. 85 and 86a.

Claim 45 is representative of the claimed invention and reads as follows:

> 45. A barbed stent for deployment within the body of a patient, comprising:
>
> a wire having at least one integrally formed barb that has not been attached to the wire during the manufacturing process, configured to engage tissue adjacent the stent;
>
> wherein the wire comprises at least one bend connecting to at least two struts such that the at least one barb points in a predetermined direction at an angle relative to a longitudinal axis of the stent, wherein the at least one barb is unbent with respect to the wire and is free of weakening due to bending.

THE REJECTIONS

The Examiner relies upon the following as evidence of unpatentability:

Anderson	US 5,800,526	Sep. 1, 1998

Appellants seek review of the Examiner's rejection of claims 45, 46, 48-50, 53, 58, and 60-62 under 35 U.S.C. § 102(b) as anticipated by Anderson.

THE ISSUE

Have Appellants shown that the Examiner erred in finding that the barbs of Anderson are unbent with respect to the stent wire? The issue turns on whether the barbs of Anderson are "necessarily" unbent with respect to the stent wire.

SUMMARY OF DECISION

We REVERSE.

PRINCIPLES OF LAW

Anticipation

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros, Inc.. v. Union Oil Co. of Cal.,* 814 F.2d 628, 631 (Fed. Cir. 1987).

Inherency

Under principles of inherency, when a reference is silent about an asserted inherent characteristic, it must be clear that the missing descriptive

matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991).

OPINION

Appellants argue that Anderson fails to teach a stent having unbent integral barbs. App. Br. 12. *See also* Reply Br. 2, 3. In response, the Examiner notes that the stent and barbs of Anderson:

> . . . are machined from a flat sheet of metal (by laser cutting or chemical etching) such that the barbs will be directed outwardly upon expansion of the stent due to removed material in the area of the barbs (see col. 9 lines 16-26 and 42-50).

Ans. 3. Further, the Examiner points to Figures 4-7 of Anderson to show that because both wire bends 18 and barbs 20 face outwardly, the barbs 20 are not bent with respect to the wire. *Id.* In other words, the Examiner appears to take the position that because material has been removed in areas of the barbs 20, during expansion of stent 10 the wire 18 will bend at these regions such that barbs 20 will be oriented outwardly but will not bend with respect to the stent wire. We disagree with the Examiner's position for the following reasons.

It is our finding that Anderson teaches a stent 10 having a plurality of integral formed barbs 20. Anderson, col. 6, ll. 41-42 and 61-66; and fig. 1. Anderson further teaches using "step etching" in the area of barbs 20 so as to,

> . . . remove portions of material so that *the barbs will bend outwardly* when the stent is expanded. In other words, step etching allows for the removal of material in highly selective areas so that upon

> radial expansion of the stent, areas having less material will have a tendency to bend or distort, such as with ***the barbs bending outwardly*** to engage the aortic valve.

Anderson, col. 9, ll. 16-26 (emphasis added).

Hence, Anderson specifically teaches that the barbs 20 bend outwardly when the stent 10 expands radially. However, having the barbs bent outwardly does not mean that the barbs themselves are bent with respect to the wire 18, as Appellants suggest. Likewise, it does not mean that it is the wire 18 that undergoes bending and not the barbs 20, as the Examiner proposes. Hence, in a first instance, we find that both situations are equally probable. However, inherency may not be established by probabilities or possibilities. *In re Oelrich,* 666 F.2d 578, 581 (CCPA 1981) (quoting *Hansgirg v. Kemmer,* 102 F.2d 212, 214 (CCPA 1939). In this case, Anderson also teaches uniform radial expansion of the stent 10 without substantial out-of-plane twisting. Anderson, col. 8, ll. 17-19. Accordingly, if the wire 18 undergoes bending to orient the barbs 20 outwardly, as the Examiner suggests, then the stent 10 will also likely undergo out-of-plane twisting, which is in contrast to Anderson's specific teachings. As such, we agree with Appellants that the barbs 20 of Anderson are not necessarily unbent with respect to the stent wire. *See* Reply Br. 3.

In conclusion, we find that the Examiner has not provided sufficient evidence to support the finding that the barbs 20 of Anderson are necessarily unbent with respect to the stent wire. Accordingly, the rejection of claims 45, 46, 48-50, 53, 58, and 60-62 under 35 U.S.C. § 102(b) as anticipated by Anderson cannot be sustained.

CONCLUSION

Appellants have shown that the Examiner erred in determining that the integral barbs of Anderson are unbent with respect to the stent wire.

DECISION

The Examiner's decision to reject claims 45, 46, 48-50, 53, 58, and 60-62 under 35 U.S.C. § 102(b) as anticipated by Anderson is reversed.

REVERSED

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